

REMARKS

No claims have been amended herein. After entry of this Letter to the Patent and Trademark Office, claims 1-9 and 11-29 are pending.

Claim Rejections under 35 U.S.C. § 112

Reconsideration is respectfully requested of the rejection of claims 1-9 and 11-29 for failing to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph. As explained below, applicant respectfully maintains that the pending claims are fully enabled. The Office states that the "specification does not enable any person skilled in the art to which it pertains, ... to use the invention commensurate in scope with these claims."¹ The Examiner asserts that the accepted usage of "prevent" is "to keep from happening" and "treat" is understood as "providing a cure or relief of an existing condition."² However, the Examiner cites a general purpose dictionary for the definition of these terms. The Court of Appeals for the Federal Circuit in Phillips v. AWH Corp.³ held that the "ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention"⁴ With this in mind, a person of ordinary skill would have been likely to refer to a technical dictionary rather than a general purpose dictionary. Thus, the terms at issue are defined in medical dictionaries as follows. "Prevent" or "preventive" means "to come before."⁵ Further, "treatment" encompasses practices which are either prophylactic or ameliorative. For example, as defined in The Signet/Mosby Medical Encyclopedia, C.V. Mosby, New York (1987) treatment is

¹ Page 2 of the Office action dated May 17, 2005.

² Page 2 of the Office action dated May 17, 2005.

³ Phillips v. AWH Corp., 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005).

⁴ See id.

⁵ Stedman's Medical Dictionary, 26th Edition, 1995.

"1. the care and overseeing of a patient to fight, reduce or prevent a disease, disorder or injury. 2. a method of fighting, reducing or preventing a disease, disorder or injury. Treatment may be pharmacologic, using drugs; surgical, involving surgery; or supportive, building the patient's strength."⁶

When read in the context of the claims and specification as a whole, and the understanding of the terms "prevent" and "treatment" in the medical arts, the meaning of preventing or treating ototoxicity, neurotoxicity, alopecia, gastrointestinal disorder, or reduced survival is to administer the protective agent of the invention to a subject in need thereof; this administration could be prior to, simultaneous with or subsequent to the onset of the condition. In any event, neither "treating" nor "relief" requires a cure, and "treating" at least is not limited to care of an existing condition.

Moreover, applicant herewith submits a declaration of Prasad Sunkara,⁷ which presents data that shows a statistically significant effect of the administration of D-methionine to combat various side effects of radiation exposure. The data presented in the declaration were obtained in tests conducted by various scientists as requested by Dr. Sunkara subsequent to the filing of the instant patent application. These data show that treatment with D-methionine before or after radiation exposure reduced the incidence of hair loss in mice undergoing experiments related to the prevention of radiation induced oral mucositis. In addition to hair loss, administration of D-methionine to mice increased the survival of jejunal crypt cells as measured per jejunal circumference upon whole body radiation exposure. This increased jejunal crypt cell survival with D-methionine administration upon whole body radiation exposure indicates that gastrointestinal side effects are decreased as compared to exposure to whole body radiation alone.

⁶ See pp. 584-585. The definition proceeds to discuss Conservative, Empiric, Expectant, Palliative, Preventive, Prophylactic or Rational treatments. Preventive Treatment is described as "designed to keep a disease from occurring or a mild disorder from becoming more severe." Prophylactic Treatment is further described as "for the prevention of a disease or disorder."

⁷ Dr. Sunkara is Chairman and CEO of Molecular Therapeutics, Inc.; Molecular Therapeutics an exclusive licensee of the present patent application.

In addition to data showing decreased hair loss and increased jejunal crypt cell survival, applicant herewith submits a declaration of the inventor, Dr. Kathleen C. M. Campbell, which presents preliminary data regarding administration of D-methionine to male Wistar rats before radiation exposure. These data show that D-methionine administration has an effect on the levels of various cochlear antioxidants and enzymes (e.g., glutathione, oxidized glutathione, superoxide dismutase, catalase, glutathione peroxidase, and glutathione reductase). But, this study did not show a significant difference in the ABR threshold shift between the rats receiving D-methionine and radiation exposure and the rats receiving radiation exposure alone. Because these data were preliminary, Dr. Campbell believes that refined experimental conditions would show a difference in auditory brainstem response (ABR) threshold between the rats receiving D-methionine and radiation and the rats receiving radiation alone.

Information Disclosure Statement

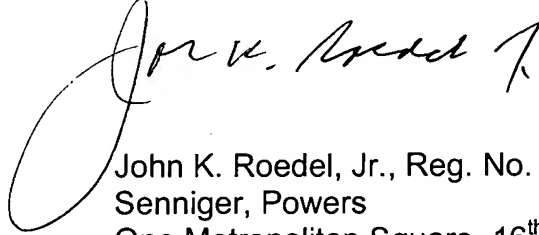
* References 8, 22, 34-37, 64 and 66 are resubmitted herewith for consideration.

CONCLUSION

Applicant submits that the present application is now in a condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John K. Roedel, Jr.", with a large, stylized initial "J" and "R".

John K. Roedel, Jr., Reg. No. 25,914
Senniger, Powers
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102

JKR/JSH/dep
*Enclosures

Mail Stop RCE via Express Mail Label No. EV416449504US